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REMARKS

This is a full and timely response to the non-final Official Action mailed June 7, 2005. Applicant hereby petitions for a one-month extension of time to respond to the Action of June 7, 2005, and authorizes payment of the corresponding fee from Deposit Account 18-0013 in the name of Rader, Fishman & Grauer PLLC. Reconsideration of the application in light of the foregoing amendments and following remarks is respectfully requested.

Claims Status:

Claims 2, 12, 13, and 22-24 were cancelled previously. No claims are added or cancelled by the present paper. Thus, claims 1, 3-11, 14-21, and 25-46 are currently pending for further action.

Allowable Subject Matter:

In the outstanding Office Action, claims 20, 21, 25-30, 32 and 40-43 were allowed. Applicant wishes to thank the Examiner for the allowance of these claims. Applicant agrees with the Examiner's conclusions regarding patentability, without necessarily agreeing with or acquiescing in the Examiner's reasoning. In particular, Applicant believes that these claims are allowable because the prior art fails to teach, anticipate or render obvious the invention as claimed, independent of how the claims are paraphrased.

35 U.S.C. § 112, First Paragraph Issues:

The recent Office Action rejected claims 44-46 under 35 U.S.C. § 112, first paragraph, as impermissible "single means" claims. These claims have accordingly been amended herein to the proper format for means-plus-function claims. These amendments are

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not intended to narrow or alter the scope of these claims in any degree. Following entry of this amendment, the rejection of claims 44-46 under § 112, first paragraph, should be reconsidered and withdrawn.

Prior Art:

In the outstanding Office Action, claims 1, 3, 4, 6, 11, 14, 15, 17, 31, 33-35, 37, 38, 44 and 45 were rejected as anticipated under 35 U.S.C. § 102(b) by U.S. Patent No. 5,199,430 to Fang et al. ("Fang"). Alternatively, claims 1, 3-6, 11, 14, 15, 17, 31, 33-35, 37, 38, 44 and 45 were rejected as anticipated under 35 U.S.C. § 102(b) by U.S. Patent No. 4,739,764 to Lue et al. ("Lue"). For at least the following reasons, these rejections are respectfully traversed.

Claim 1 recites:

A method for treating a patient with urgency, frequency, urinary incontinence, and/or fecal incontinence comprising:
providing at least one stimulator having at least two electrodes;
implanting the at least one stimulator adjacent to at least one parasympathetic target that innervates at least one urinary, gastrointestinal, and/or other pelvic structure;
providing operating power to the at least one stimulator;
providing stimulation parameters to the at least one stimulator;
generating inhibitory stimulation pulses in accordance with the stimulation parameters; and
delivering the inhibitory stimulation pulses to nerves and tissue adjacent to the at least two electrodes to inhibit parasympathetic input to said urinary, gastrointestinal, and/or other pelvic structure *in order to treat urgency, frequency, urinary incontinence, and/or fecal incontinence;*
wherein the stimulator has a size and shape suitable for placement adjacent to the at least one parasympathetic target.
(emphasis added).

Independent claim 31 similarly recites:

A method for treating a patient with urgency, frequency, urinary incontinence, and/or fecal incontinence comprising the steps of:
providing at least one means for stimulating tissue;

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implanting the at least one stimulating means adjacent to at least one parasympathetic target that innervates at least one urinary, gastrointestinal, and/or other pelvic structure;
providing operating power to the at least one stimulating means;
providing stimulation parameters to the at least one stimulating means;
generating inhibitory stimulation pulses in accordance with the stimulation parameters; and
delivering the inhibitory stimulation pulses to nerves and tissue adjacent to the at least one stimulating means to inhibit parasympathetic input to said urinary, gastrointestinal, and/or other pelvic structure in order to treat urgency, frequency, urinary incontinence, and/or fecal incontinence;
wherein the stimulating means has a size and shape suitable for placement adjacent to the at least one parasympathetic target.
(emphasis added).

In contrast, Fang fails to teach or suggest (1) implanting the at least one stimulator or stimulating means adjacent to at least one parasympathetic target that innervates at least one urinary, gastrointestinal, and/or other pelvic structure; and (2) delivering stimulation pulses to treat "urinary incontinence and/or fecal incontinence." Each of these aspects of claims 1 and 31 will be discussed below.

As explained in Applicant's specification, prior art techniques and implantable stimulators "have different forms, but are usually comprised of an implantable control module to which is connected a series of leads that must be routed to nerve bundles in either the sacral roots emanating from the spinal cord, or the nerves supplying muscles, skin or other structures in the pelvic region. The implantable devices are relatively large and expensive. In addition, they require significant surgical procedures for placement of electrodes, leads, and processing units." (Applicant's specification, p. 3, last paragraph).

In this vein, Fang teaches "cuff electrodes" that are implanted in a relatively invasive procedure in which the cuffs must be wrapped around a nerve to be stimulated. (Fang, col. 4, lines 39-42). Consequently, Fang is merely an example of the prior art described and distinguished on page 3 of Applicant's specification.

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Thus, Fang fails to teach or suggest the claimed method including “implanting the at least one stimulator adjacent to at least one parasympathetic target that innervates at least one urinary, gastrointestinal, and/or other pelvic structure; ... *wherein the stimulator has a size and shape suitable for placement adjacent to the at least one parasympathetic target.*” (emphasis added). As further explained in Applicant’s specification, Applicant’s claimed approach provides “associated advantages over known treatments in terms of reduced expense and opportunity for infection or other complications.” (Applicant’s specification, p. 7, first paragraph). For at least these reasons, the teachings of Fang are distinguished from the recited features of claims 1 and 31.

Additionally, Fang fails to teach or suggest a method that includes treating urinary or fecal incontinence as claimed. Rather, Fang teaches a method that enables, rather than prevents, the release of urine from the bladder. According to Fang, “[a]nother advantage of the present invention is that it enables the bladder to be drained without operating detrusor and sphincter muscles at cross purposes.” (Fang, col. 3, lines 3-5). This is accomplished by the Fang system through “[a]ction potentials [that] are initiated on a nerve bundle which includes nerve fibers flowing to detrusor muscles and to the urethral sphincter. Action potentials are caused to emanate from the electrode upstream toward the spinal cord on at least the nerve fibers destined for the urethral sphincter muscle for collision blocking action potentials coming from the spinal cord such that the urethral sphincter is allowed to relax. Concurrently, action potentials are produced flowing downstream on the nerve fibers connected with the detrusor muscles but not on the nerve fibers connected with the urethral sphincter.” (Fang, col. 2, lines 48-61).

Consequently, Fang fails to teach or suggest all the features of claims 1 and 31. Fang fails to teach (1) implanting the at least one stimulator adjacent to at least one

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parasympathetic target that innervates at least one urinary, gastrointestinal, and/or other pelvic structure; and (2) delivering stimulation pulses to treat “urinary incontinence and/or fecal incontinence.” “A claim is anticipated [under 35 U.S.C. § 102] only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987) (emphasis added). See M.P.E.P. § 2131. For at least these reasons, the rejection of claims 1 and 31 and its dependent claims based on Fang should be reconsidered and withdrawn.

Turning to Lue, the teachings of Lue are similarly inapplicable to claims 1 and 31. Specifically, Lue fails to teach or suggest (1) implanting the at least one stimulator adjacent to at least one parasympathetic target that innervates at least one urinary, gastrointestinal, and/or other pelvic structure; and (2) delivering the inhibitory stimulation pulses to nerves and tissue adjacent to the at least two electrodes to inhibit parasympathetic input to said urinary, gastrointestinal, and/or other pelvic structure in order to treat urgency, frequency, urinary incontinence, and/or fecal incontinence.”

Lue, like Fang, teaches the use of cuff electrodes that are wrapped around a nerve to be stimulated, with the cuff electrode being connected by relatively long leads to a stimulator presumably located elsewhere in the body. See Lue, Figs. 15 and 16. Thus, Lue, like Fang, fails to teach or suggest a method that includes “implanting the at least one stimulator adjacent to at least one parasympathetic target that innervates at least one urinary, gastrointestinal, and/or other pelvic structure.”

Additionally, Lue does not teach a method of treating incontinence by delivering inhibitory stimulation pulses to inhibit parasympathetic input to said urinary, gastrointestinal, and/or other pelvic structure, as claimed. Rather, Lue teaches a method for “treating

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incontinence by increasing sphincter tonus.” (Lue, abstract). This is accomplished, for example, by “direct stimulation of a sphincter muscle or by modulating reflex control mechanisms so that more effective sphincter tonus results.” (Lue, col. 8, lines 30-35).

Consequently, Lue, like Fang, fails to teach or suggest all the features of claims 1 and 31. Lue fails to teach (1) implanting the at least one stimulator adjacent to at least one parasympathetic target that innervates at least one urinary, gastrointestinal, and/or other pelvic structure; and (2) delivering the inhibitory stimulation pulses to nerves and tissue adjacent to the at least two electrodes to inhibit parasympathetic input to said urinary, gastrointestinal, and/or other pelvic structure in order to treat urgency, frequency, urinary incontinence, and/or fecal incontinence.” “A claim is anticipated [under 35 U.S.C. § 102] only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987) (emphasis added). See M.P.E.P. § 2131. For at least these reasons, the rejection of claims 1 and 31 and its dependent claims based on Lue should also be reconsidered and withdrawn.

Independent claim 11 recites:

A method for treating a patient with urinary and/or fecal dysfunction comprising:
providing at least one stimulator having at least two electrodes;
implanting the at least one stimulator adjacent to at least one parasympathetic target that innervates at least one urinary, gastrointestinal, and/or other pelvic structure;
providing operating power to the at least one stimulator;
providing stimulation parameters to the at least one stimulator;
generating inhibitory stimulation pulses with said at least one stimulator in accordance with the stimulation parameters;
delivering the inhibitory stimulation pulses to nerve fibers adjacent to the at least two electrodes to inhibit parasympathetic input to said urinary, gastrointestinal,

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and/or other pelvic structure in order to treat urgency, frequency, urinary incontinence, and/or fecal incontinence;

generating excitatory stimulation pulses with said at least one stimulator in accordance with the stimulation parameters; and

delivering the excitatory stimulation pulses to nerves and tissue adjacent to the at least two electrodes in order to treat urinary and/or fecal retention;

wherein the stimulator has a size and shape suitable for placement adjacent to the at least one parasympathetic target.

Claim 11 is clearly allowable over the teachings of Fang and Lue for at least the same reasons given above with respect to claims 1 and 31. Additionally, in rejecting claim 11, the recent Office Action argued "since the excitation potentials can either be blocked or allowed to propagate both upstream and downstream (depending upon whether allowing voiding or preventing), the application of both excitatory and inhibiting pulses would be provided by the teachings of Fang et al." (Action of 6/7/05, p. 3).

To clarify this point, Applicant has amended claim 11 to expressly recite that the inhibitory and excitatory pulses are generated with one or more implanted stimulators and are not merely the result of failing to block naturally-occurring pulses already traveling on a nerve. Thus, claim 11 is now further distinguished from the teachings of the prior art as cited in the recent Office Action, and for the foregoing reasons and this additional reason, the rejection of claim 11 and its dependent claims should be reconsidered and withdrawn.

Independent claim 33 recites:

A method of treating a patient with a bowel dysfunction, said method comprising:

applying one or more inhibitory stimulation pulses to a parasympathetic nerve within said patient with an implanted stimulator in accordance with one or more stimulation parameters to treat said bowel dysfunction.

Claim 44 recites similar subject matter in the form of a means-plus-function claim.

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Independent claim 37 recites:

A method of treating a patient with at least one bowel dysfunction, said method comprising:

applying one or more inhibitory stimulation pulses and one or more excitatory stimulation pulses to a parasympathetic nerve within said patient with an implanted stimulator in accordance with one or more stimulation parameters;

wherein said inhibitory stimulation pulses are configured to treat fecal incontinence and said excitatory stimulation pulses are configured to treat fecal retention.

Claim 45 recites similar subject matter in the form of a means-plus-function claim.

In contrast, Fang, as described above, teaches a method of voiding a urinary bladder.

Fang does not teach or suggest a method of treating a bowel dysfunction as claimed. For at least this reason, the rejection of claims 33-45 based on Fang should be reconsidered and withdrawn.

Turning to Lue, Lue does not teach or suggest "applying one or more inhibitory stimulation pulses to a parasympathetic nerve within said patient with an implanted stimulator in accordance with one or more stimulation parameters to treat said bowel dysfunction" as claimed in claim 33. Lue also does not appear to teach the applying of inhibitory and excitatory stimulation pulses as recited in claim 37.

In the recent Office Action, Lue is cited at col. 8, lines 50-53 as teaching the application of pulses to nerves to influence the nerves by "inhibition or facilitation." (Action of 6/7/05, p. 3). This, however, is actually a mischaracterization of what Lue teaches. The portion of Lue cited refers to the natural interaction of nerves and musculature, *not* to any pulses applied by an implanted stimulator as implied by the Office Action. According to Lue, "[t]he term 'reflex control mechanisms' means those nerve bundles that control interrelated activity between bladder B and pelvic floor musculature (primarily levator ani muscle D) as they can reflexively influence each other by either inhibition or facilitation." (Lue, col. 8,

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lines 49-53). Consequently the Office Action has failed to indicate how or where Lue actually teaches the subject matter recited in claims 33-45

Thus, Lue does not appear to unambiguously teach the subject matter of claims 33, 37, 44, and 45. For at least this reason, the rejection of claims 33-45 based on Lue should be reconsidered and withdrawn.

Independent claim 46 recites:

A system for treating a patient with a bowel dysfunction, said system comprising:
means for applying one or more inhibitory stimulation pulses to *a sympathetic nerve* within said patient; and
means for generating said stimulation pulses in accordance with one or more stimulation parameters;
wherein said bowel dysfunction comprises fecal retention.
(emphasis added).

In contrast, none of the cited prior art appear to teach or suggest a system for treating bowel dysfunction as claimed including means for stimulating a sympathetic nerve. The recent Office Action does not appear to address this feature of claim 46. Consequently, the rejection of claim 46 should be reconsidered and withdrawn.

The Office Action also rejected dependent claims 5, 10, 16 and 19 as unpatentable under 35 U.S.C. § 103(a) over the teachings of Fang taken alone. This rejection is respectfully traversed for at least the same reasons given above with respect to the independent claims from which these claims ultimately depend.

Additionally, this rejection is respectfully traversed because the prior art of record does not teach or suggest stimulation of the particular nerves cited in the these claims. According to the Examiner, stimulating the claimed nerves would have been obvious to one

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of ordinary skill in the art. (Action of 6/7/05, p. 4). However, the examiner has the initial burden of demonstrating that all the claimed features of the invention are taught by the prior art. *In re Fine*, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). Where the examiner relies on a single reference under § 103, it is insufficient to merely state that it would be obvious, or a mere matter of design choice, to modify the disclosure to include the features of the claimed invention. *In re Mills*, 16 USPQ2d 1430, 1432 (Fed. Cir. 1990). "To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)." M.P.E.P. § 2143.03. (emphasis added). Accord. M.P.E.P. § 706.02(j).

Consequently, Applicant requests that prior art be made of record supporting the rejection of claims 5, 10, 16 and 19, or the rejection reconsidered and withdrawn.

Claims 7-9, 18, 36 and 39 were rejected as unpatentable under 35 U.S.C. § 103(a) over the teachings of Fang or Lue in combination with those of Sawan et al. (of record). This rejection is respectfully traversed for at least the same reasons given above with respect to the independent claims from which these claims ultimately depend.

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Conclusion:

For the foregoing reasons, the present application is thought to be clearly in condition for allowance. Accordingly, favorable reconsideration of the application in light of these remarks is courteously solicited. If any fees are owed in connection with this paper, which have not been elsewhere authorized, authorization is hereby given to charge those fees to Deposit Account 18-0013 in the name of Rader, Fishman & Grauer PLLC. If the Examiner has any comments or suggestions which could place this application in even better form, the Examiner is requested to telephone the undersigned attorney at the number listed below.

Respectfully submitted,

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